REMARKS

Claims 1-49 are pending in the present application. Claims 1-49 are method claims directed to a method making a complex in a sample between a prion protein and a prion binding material. Claim 1 is recited below:

Claim 1. A method of forming a complex between a prion protein and a prion protein binding material in a sample comprising contacting the sample with the prion protein binding material under conditions allowing formation of the complex between the prion protein and the prion protein binding material, wherein the prion binding material comprises a polymer matrix to which is bound a functional group, wherein the functional group is a hydrophilic, a hydrophobic, or an amphiphilic functional group.

The Examiner has imposed a 41 way restriction and election of species requirement among the claims alleging the presence of 41 distinct inventions and/or species. In particular, the Examiner has issued a Restriction and/or Election of Species Requirement based on the structure of the polymer matrix and the functional group of the prion binding materials, the type of the prion proteins that bind to the binding material, and the type and animal origin of samples that contain a prion protein.

Each of the Examiner's Restriction and/or Election of Species requirements and Applicants response thereto is discussed in turn below.

I. Restriction to One Functional Group On The Binding Material

On page 2 of the Office Action, the Examiner has issued a Restriction and/or Election of Species Requirement under 35 U.S.C. § 121 to one of the following inventions:

Group 1. Claims 1-6, 9-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of an amine group, classified in class 524, subclass 722.

Group 2. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a sulfite group, classified in class 558, subclass 59.

Group 3. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of sulfonyl group, classified in class 522, subclass 59.

Group 4. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a tresyl group, classified in class 520, subclass 1.

Group 5. Claims 1-6, 8, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of an alkyl group, classified in class 524, subclass 46.

Group 6. Claims 1-7, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of an aromatic group, classified in class 524, subclass 471.

Group 7. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a siloxane group, classified in class 524, subclass 731.

Group 8. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a fluorinated group, classified in class 524, subclass 795.

Group 9. Claims 34-49 drawn to a method of forming a complex with a prion protein using a binding material comprising aluminum, classified in class 424, subclass 682.

Group 10. Claims 34-49 drawn to a method of forming a complex with a prion protein using a binding material comprising silica, classified in class 424, subclass 704.

Specifically, the Examiner alleges that inventions 1-10 are unrelated because they do not have structural identity and such structural identity is required for binding a particular prion protein. The Examiner further contends that inventions are different if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. The Examiner relies on MPEP § 806.04, MPEP § 808.01 to support her position.

Applicants elect the invention of Group 1, with traverse.

Applicants respectfully traverse the Restriction on the ground that no adequate reasons and/or examples have been provided to support the conclusion of patentable distinctness between Applicants' claimed subject matter. Applicants respectfully submit that the functional groups of the binding materials of the invention as claimed have the same mode of operation and same function (*e.g.*, assist binding the polymeric binding material to bind with the prion protein), and have the same effect (form the complex between the polymeric binding material and the prion protein). Thus, while Applicants take no position regarding the patentable distinctness of the functional groups enumerated by the Examiner, Applicants submit that because no adequate reasons were offered in the Restriction Requirement to support a conclusion of patentable distinctness, the Restriction Requirement is insufficient, M.P.E.P. § 803. The indication that different classifications are involved in searching the application is merely a restatement of an unsupported conclusion of patentable distinctness.

Additionally, Applicants submit that a proper Restriction practice requires that there would be "serious burden on the Examiner if Restriction is not required" (M.P.E.P. § 802(2)), which Applicants respectfully submit is not the case in the present instance.

Although the Examiner asserts different classifications for the claims of Groups 1-10 apparently to support the contention that a serious burden exists, Applicants respectfully submit that the search of a binding material having a functional group made up of an alkyl group and the binding material having a functional group made up of an aromatic group requires similar searches. Indeed several of the Groups indicated by the Examiner belong to the same Class (*i.e.*, Groups 5-8 and 9-10).

Accordingly, Applicants respectfully submit that the Restriction Requirement is improper, and it should be withdrawn. In the event that the Examiner's Restriction Requirement is made final, Applicants reserve the right to file divisional applications directed to the subject matter of Groups 2-10.

Accordingly, Applicants respectfully submit that the Restriction Requirement is improper, and that it should be withdrawn.

II. Restriction to One Form of Prion Protein

On page 2 of the Office Action, the Examiner has issued a Restriction and/or Election of Species Requirement under 35 U.S.C. § 121 to one of the following inventions:

(Al) PrPc.

(Bl) PrPSc

(Cl) PrPr

(D1) PrPres.

The Examiner contends that Applicants need to select the form of the prion protein that is to be detected by the binding material. Specifically, the Examiner contends that structural identity of the prion polypeptide is required for detection or disease prognosis and the different structures represented by the same sequences have different effects.

Applicants elect the prion protein of Group (B1) directed to PrPSc, with traverse.

Applicants respectfully traverse the Restriction Requirement on the ground that no adequate reasons and/or examples have been provided to support the conclusion of

patentable distinctness between Applicants' claimed prion proteins. The Examiner has mischaracterized the claims as being directed to a method of disease prognosis or detection. Applicants respectfully submit that the present invention as claimed is directed to a method of making a complex between a prion protein and a binding material. The claims are not limited to a specific prion protein and all forms of prion proteins are encompassed within the scope of the invention as claimed. Thus, while Applicants take no position regarding the patentable distinctness of prion proteins enumerated by the Examiner, Applicants submit that because no adequate reasons were offered in the Restriction Requirement to support a conclusion of patentable distinctness, the Restriction Requirement is insufficient, M.P.E.P. § 803.

Accordingly, Applicants respectfully submit that the Restriction Requirement is improper, and that is should be withdrawn.

III. Restriction To One Type of Polymer Matrix.

On Page 2-3 of the Office Action, the Examiner has issued a Restriction and/or Election of Species Requirement under 35 U.S.C. § 121 to one of the following polymer matrixes used as a polymeric binding material.

(A2) Polymethylacrylate (TOYOPEARLTM Amino 650), classified in class 429, subclass 317.

(B2) Methylacrylate (TOYOPEARLTM Amino 650), classified in class 524, subclass 329.7.

(C2) FRACTOGELTM EMD, classified in class 520, subclass 1.

(D2) TOYOPEARLTM, classified in class 520, subclass 1.

(E2) TSK-GELTM, classified in class 520, subclass 1.

Specifically, the Examiner contends that Inventions A2-E2 are unrelated because they have different modes of operation, different functions, or different effects. The Examiner further contends that where structural identity is required, such as for binding a particular form of the prion protein, the different structures represented by different matrixes have different binding effects on the prion protein.

Applicants elect the polymer matrix of Group (A2) directed to Polymethylacrylate (TOYOPEARLTM Amino 650), with traverse.

Applicants respectfully traverse the Restriction on the ground that no adequate reasons and/or examples have been provided to support the conclusion of patentable distinctness between Applicants' claimed polymeric matrixes. The invention as claimed encompasses polymeric matrixes capable of forming a complex with a prion protein in a sample. Contrary to the Examiner's readings of the claims, the degree of binding effect or differences in binding strength among the polymeric matrixes are not the subject of the invention as claimed. Thus, while Applicants take no position regarding the patentable distinctness of polymeric matrixes enumerated by the Examiner, Applicants submit that because no adequate reasons were offered in the Restriction Requirement to support a conclusion of patentable distinctness, the Restriction Requirement is insufficient, M.P.E.P. § 803.

Applicants further submit that a proper Restriction practice requires that there would be "serious burden on the Examiner if Restriction is not required" (M.P.E.P. § 802(2)), which Applicants respectfully submit is not the case in the present invention as claimed. Although the Examiner asserts different classifications for the Groups A2- E2 apparently to support the contention that a serious burden exists, Applicants respectfully submit that the search of a polymer matrix of Polymethylacrylate of Group A2 and the Methylacrylate of Group B2 requires virtually identical searches. Indeed, several of the Groups indicated by the Examiner belong to the same Class (*i.e.*, Groups C2-E2).

Accordingly, Applicants respectfully submit that the Restriction Requirement is improper, and that it should be withdrawn.

IV. Restriction to One Animal Origin of The Sample

On Page 4 of the Office Action, The Examiner has issued an Election of Species Requirement under 35 U.S.C. § 121 to animal species from which the samples have derived from. Specifically, the Examiner contends that claims directed to "the sample" are generic. The Examiner's classification of the animal species is as follows:

(SA3) human

(SB3) bovine

(SC3) ovine

(SD3) Porcine

(SE3) equine

(SF3) Murine

(SG3) cervidae

Applicants elect species of Group SA3 (human), with traverse.

Applicants respectfully traverse the Election of Species Requirement on the ground that no adequate reasons and/or examples have been provided to support the conclusion of patentable distinctness between Applicants' samples that are subjected to the method of forming a complex of the invention as claimed. The invention as claimed encompasses any animal samples that may contain a prion protein. Far from being different inventions, these samples are merely separate facets of the same general concept; *i.e.*, forming a complex between the prion protein and a protein binding material. The various claims of Groups SA3-SG3 are thus related in operation and effect, and cannot be independent.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the election of species requirement among different animal samples.

V. Restriction to One Type of Sample

On Page 4 of the Office Action, The Examiner has issued an Election of Species Requirement under 35 U.S.C. § 121 to one type of sample, as follows:

(S1) Biological sample: blood derived sample

(S2) Biological sample: brain derived sample

(S3) Biological sample: bodily fluid derived sample

(S4) Biological sample: collagen extract

(S5) Biological sample: gland extract

(S6) Biological sample: tissue homogenate or extract

(S7) Food product/food/or nutritional supplement

(S8) Environmental product

(S9) Water sample

(S10) Pharmaceutical compositions

(S11) Therapeutic composition

(S12) Cosmetic composition

Specifically, the Examiner contends that claims directed to "the sample" are generic and requests the Applicants to elect one type of a sample for examination. The Examiner has provided no reasoning as to why she believes that the use of any type of sample within the scope of the claims is generic.

Applicants elect species of Group S1 (blood derived samples), with traverse. Applicants respectfully traverse the Election of Species requirement on the same ground as stated under Section IV above. Specifically, Applicants submit that no adequate reasons and/or examples have been provided by the Examiner to support the conclusion of patentable distinctness among different samples that are subjected to the method of forming a complex of the invention as claimed. Additionally, the Examiner has provided no reasons as to why a serious burden would be imposed on the Examiner to examine the claimed method of making a complex between a prion protein and a prion protein binding material in a sample, wherein the sample may be any sample, derived from any biological and/or non-biological sources. As stated in Section IV above, these samples are merely separate facets of the same general concept; *i.e.*, forming a complex between the prion protein and a protein binding material. The various claims of Groups S1-S12 are thus related in operation and effect, and cannot be independent.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the Election of Species Requirement among different samples.

CONCLUSION

The search and examination of Claims 1-49 of the present invention in one application do not present serious burden on the Examiner. In light of the election of

several Groups above, Applicants respectfully request that the claims of these Groups be recombined and examined concurrently in the present application. Withdrawal of the Restriction and/or Election of Species requirement with respect to all Groups enumerated by the Examiner is therefore proper.

Applicants respectfully remind Examiner that MPEP §803 places the burden squarely on the examiner to "provide reasons and/or examples to support conclusions" presented in a Restriction and/or Election of Species Requirement. *See* also MPEP §808.02(B). Thus, if Examiner maintains any or all of the present the restriction requirement, Applicants respectfully request that Examiner clearly articulate reasons and/or provide examples and evidence in support of her position.

Applicants' undersigned attorney may be reached by telephone at (301) 767-0134. All correspondence should be directed to our address given below.

Respectfully submitted,

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